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In re BROADENING REISSUE patent application of:
FAOUR, J. et al.

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For: Multi-layered osmotic device

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Sir:

STATEMENT OF STATUS and PRELIMINARY AMENDMENT

Applicants claim the benefit of priority of Argentine application P97 01 02351, filed May 30, 1997. During prosecution of the application underlying the original patent for which a reissue patent is sought, the patentee failed to provide a certified copy and verified translation of the priority Argentine patent application and therefore failed to perfect the claim for priority in the original patent. Applicants provide herewith a certified copy and verified translation of the priority application. Moreover, Applicants have claimed, in the Reissue Declaration, the benefit of priority of the Argentine application.

Applicants hereby surrender the ribboned original patent 6,004,582, which is being filed concurrently herewith. Applicants request that the ribboned original patent be kept by the Patent Office until such time as a reissue patent is granted or until the present reissue application is abandoned. If the reissue application is abandoned, applicants request return of the ribboned original patent.

Filed herewith is a copy of the parent patent in double column format. The copy includes the front page, drawings, specification and claims of the patent. Only claim 1 has been amended.

Applicant hereby submits the following preliminary amendment, which is being filed concurrently with the above-identified broadening reissue application. Please amend the

application as follows.

Statement of Status and Support for all Changes to the Claims

Claims 1-49 remain in this application. Claim 1 has been amended. New claims 24-49 have been added. No claims have been canceled. Consideration of the claims is respectfully requested. Attached hereto is a copy of claim 1 as amended and claims 24-49 as added.

Claim 1 has been amended to clarify the antecedent bases of the term "drug" and the first and second active agents. The term "or" has been added between the terms "completely erodible" and "water soluble" in subsection c) of the claim. The addition of the term "or" to require the subject matter of an "inert, completely water soluble or erodible polymer coat" is clearly supported by the specification (Col 5, lines 3-5, 8-10, 44-46, and 53-55).

New claim 24 is broader than claim 1. Claim 24 includes the same subject matter as does claim 1 as amended herein and substantially as issued, except that claim 24 covers embodiments wherein the inert, completely erodible or water soluble polymer coat does not necessarily require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate). Applicant is not attempting to recapture subject matter surrendered during prosecution of the application underlying the issued patent. As indicated in the Examiner's Amendment accompanying the Notice of Allowability mailed September 13, 1999, the term "completely erodible", as regards the inert coat, was added to claim 1 by examiner's amendment. This amendment was agreed to, by the undersigned agent, during an interview with the examiner conducted on September 2, 1999, an Interview Summary (Paper 13) of which was prepared by the examiner. The Interview Summary indicates the examiner suggested that claim 1 be amended "to reflect the complete dissolution of polymeric coat, which applicants consider as a distinguishing feature, as opposed to prior art." The undersigned then authorized the examiner to amend claim 1 as indicated. It was the position of the examiner that the key distinguishing feature of the claimed osmotic device was the inert, completely erodible or water soluble polymer coat. It was not the examiner's position that the inert coat must comprise poly(vinylpyrrolidone)-(vinyl acetate) copolymer in order to render claim 1 patentable, since the presence or absence of the poly(vinylpyrrolidone)-(vinyl acetate) copolymer was not considered as being relevant to the patentability of the claims.

The record shows that Applicant believed the essence of the invention to be more than the presence of poly(vinylpyrrolidone)-(vinyl acetate) copolymer in the inert coat. In the amendment mailed August 17, 1999, Applicant distinguished the claimed invention from the prior art of

Guittard '604 (US 4,576,604), Savastano '584 (US 5,681,584) and Funakoshi '099 (US 4,335,099) by arguing that "the microporous lamina [of Guittard '604] acts in concert with the semipermeable membrane 'to form an integral laminated wall, that maintains its physical and chemical integrity and does not separate into lamina' [emphasis added] during operation of the device." Applicant added, "Even though the microporous lamina [of Guittard '604] can comprise water soluble or cross-linked PVT, the microporous lamina must form an integral wall with the semipermeable membrane and the integral laminated wall must maintain its physical and chemical integrity and not separate into lamina during operation of the device." (See page 4, second paragraph.) Applicant argued, "Even though the semipermeable membrane (B) [of Applicant's device] maintains its chemical and physical integrity during operation of the device, the water soluble PVP-VA-containing lamina (C) does not maintain its physical and chemical integrity during operation of the device." (See page 4, third paragraph.) Accordingly, both Applicant and the examiner believed a key distinguishing feature of the invention to be the completely erodible or water soluble polymer coat located between the semipermeable membrane and the external drug-containing coat.

The broadened scope of claim 24 is supported by the specification, which indicates the inert coat can comprise any of a number of different polymers provided the inert coat is completely erodible or water soluble. The detailed description sets forth the necessary characteristics of the inert polymeric coat. More specifically, the specification states as follows:

> The polymeric coat (3) covering the semipermeable wall (4) and blocking the passageway (6) is made of synthetic or natural material which, through selective dissolution or erosion shall allow the passageway to be unblocked thus allowing the process of osmotic delivery to start. This slow or fast dissolving polymer coat (3) can be impermeable to a first external fluid, while being soluble in a second external fluid. This property can help to achieve a controlled and selective release of the active compound in the nucleus.
>
> The polymer coat (3) will generally comprise an inert and non-toxic material which is at least partially, and preferably substantially completely, soluble or erodible in an environment of use. The polymer coat (3) can be soluble in one or more environments of use. (Col. 6, lines 54-66)

Moreover, Examples 4 (Col. 20, lines 62-67), 7 (Col. 22, lines 8-12), and 8 (Col. 22, lines 44-50) include exemplary formulations wherein the inert coat is completely erodible or water soluble but does not comprise poly(vinylpyrrolidone)-(vinyl acetate) copolymer.

Applicants note that the requirement of poly(vinylpyrrolidone)-(vinyl acetate) copolymer

in the inert completely erodible or water soluble coat was present in the originally filed claims and that this limitation was not added to the claims during prosecution.

Accordingly, the scope of claim 1 as issued is unnecessarily narrow as it requires the presence of poly(vinylpyrrolidone)-(vinyl acetate) copolymer in the inert coat, and new claim 24, therefore, does not require that the inert coat comprise poly(vinylpyrrolidone)-(vinyl acetate) copolymer.

New claim 25 is broader than claim 1 of the original patent. Claim 25 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. The limitation regarding the physical properties of the semipermeable membrane was present in the originally filed claims and was not introduced or argued during prosecution. Claim 25 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. The comments above concerning the absence of this limitation in claim 24 apply here as well. Subsection d) of claim 25 does not specify "a controlled delivery of the one or more active agents", since the controlled and continuous release of the first active agent is already specified in subsection a) and the immediate release of the second active agent is specified in subsection d). In terms of the release of active agent, the subject matter of subsection d) of claim 25 is narrower than the subject matter of subsection d) of claim 1 or claim 24.

New claim 26 is broader than claim 1 of the original patent. Claim 26 does not specify the physical properties of the semipermeable membrane. The comments above concerning the same for claim 25 are applicable here as well. Claim 26 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. The comments above concerning the absence of this limitation in claim 24 apply here as well. Subsection c) of claim 26 requires "at least one" preformed passageway in the wall. This limitation is supported by the specification, which states as follows:

> "Although the osmotic device (1) is depicted with a single passageway (6), it is contemplated that a device according to the invention can comprise at least one or more passageways including two, three, four, five, six, seven, eight, nine, ten or more passageways." (See Col. 8, lines 62-67.)

Subsection d) of claim 26 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). In this regard, the relevant comments concerning subsection d) of claim 25 apply here as well.

Subsection d) of claim 26 is broader than subsection d) of claim 1, as claim 26 does not limit the release profile of the second active agent. The release profile of the second active agent was not amended or argued during prosecution. Subsection d) of claim 1 specifies "immediate release of the drug [second active agent]" and "the controlled delivery of the one or more active agents". Accordingly, the scope of claim 1 is presumably limited to the controlled release of the first active agent and the immediate release of the second active agent. The Applicants failed to claim other embodiments wherein the second active agent has a release profile other than an immediate release profile. The specification, however, clearly supports and enables embodiments wherein the second active agent has a release profile other than an immediate release profile. The specification reads as follows:

> The external coat (2) contains a second active agent that may or may not be the same as a first active agent in the core (5). The second active agent is available for immediate, slow, delayed, sustained, pseudo-first order, pseudo-zero order, timed, controlled release or combinations thereof. (Col. 6, lines 11-15)

Moreover, the specification includes lists of materials (Col. 6, lines 23-41) that can comprise the external coat (2). The artisan of ordinary skill will recognize that these materials include materials that are used in formulations to provide an immediate, slow, delayed, sustained, pseudo-first order, pseudo-zero order, timed, and/or controlled release of an active agent depending upon the material or combination of materials used.

New claim 27 is broader than claim 1 of the original patent. Claim 27 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. The comments above concerning the same for claim 25 are applicable here as well. Claim 27 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. The comments above concerning the absence of this limitation in claim 24 apply here as well. Subsection c) of claim 26 also requires "at least one" preformed passageway in the wall. The comments above concerning the absence of this limitation in claim 26 apply here as well. Subsection d) of claim 27 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). Subsection d) also expands the release profile of the second active agent to include "immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent". The comments above concerning the release profile of the second active agent in claim 26 apply here

as well.

New claim 28 depends from and includes the subject matter of new independent claims 24-27. Claim 28 includes subject matter disclosed in issued claim 7.

New claim 29 depends from and includes the subject matter of new independent claims 24-27. Claim 29 includes subject matter disclosed in issued claim 8.

New claim 30 depends from and includes the subject matter of new independent claims 24-27. Claim 30 includes subject matter disclosed in issued claim 10.

New claim 31 depends from and includes the subject matter of new independent claims 24-27. Claim 31 includes subject matter disclosed in issued claim 15.

New claim 32 depends from and includes the subject matter of new independent claims 24-27. Claim 32 includes subject matter disclosed in issued claim 17.

New claim 33 depends from and includes the subject matter of new independent claims 24-27. Claim 33 includes subject matter disclosed in issued claim 18.

New claim 34 depends from and includes the subject matter of independent claims 1, 24-27. Claim 34 limits the first and second active agent to particular types of agents. Since the first and second active agents can be the same or different, they are independently selected at each occurrence. The list of types is set forth in the specification (Col. 13, lines 54-67). The specification includes exemplary formulations wherein the first and second active agents are the same (Example 1) or different (Examples 2-4, 6 and 8).

New claim 35 depends from and includes the subject matter of independent claims 1, 24-27. Claim 35 also limits the first and second active agent to particular types of agents. Since the first and second active agents can be the same or different, they are independently selected at each occurrence. The list of types is set forth in the specification (Col. 13, lines 41-49).

New claim 36 depends from and includes the subject matter of independent claims 25, 26 or 27. Claim 36 requires an inert, completely erodible or water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer. The subject matter of claim 36 is found throughout the specification and in claim 1 as originally filed and as issued.

New claim 37 depends from and includes the subject matter of claim 36. Claim 37 requires the presence of a second polymer in the polymer coat. This subject matter is supported by the specification as originally filed (Cols. 7-8).

New claim 38 depends from and includes the subject matter of claim 36. Claim 38

includes the subject matter of issued claim 21.

New claim 39 depends from and includes the subject matter of claim 38. Claim 39 includes the subject matter of issued claim 23.

New claim 40 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 40 requires the presence of at least two different polymers in the polymer coat. This subject matter is supported by the specification as originally filed (Cols. 7-8; Examples 4, 7 and 8).

New claim 41 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 41 requires that the release of the first active agent be delayed with respect to release of the second active agent. Accordingly, release of the first active agent will begin after release of the second active agent has begun. This subject matter is supported by the issued claims 1 and 19 and by the specification as originally filed (Col. 5, lines 9-13, 35-39, 44-46 and 53-57).

New claim 42 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 42 includes the subject matter of issued claim 12.

New claim 43 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 43 includes the subject matter of issued claim 13.

New claim 44 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 44 includes the subject matter of issued claim 11.

New claim 45 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 45 includes the subject matter of issued claim 14.

New claim 46 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 46 includes the subject matter of issued claim 9.

New claim 47 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 47 limits the first and second active agents to a particular combination of active agents, wherein the first active agent is decongestant and the second active agent is an antihistamine. This combination of types is supported by issued claim 11 and by the specification, which includes an exemplary formulation (Example 2) containing pseudoephedrine (a decongestant) and loratadine (an antihistamine; Col. 14, lines 33-35) and another exemplary formulation (Example 4) containing pseudoephedrine and astemizole (an antihistamine).

New claim 48 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 48 limits the first and second active agents to a particular combination of active agents,

wherein the first active agent is an antihypertensive agent and the second active agent is a different second antihypertensive agent. This combination of types is supported by issued claim 14 and by the specification, which includes an exemplary formulation (Example 6) containing diltiazem (a calcium channel blocker antihypertensive agent) and enalapril (an ACE (angiotensin converting enzyme II) inhibitor antihypertensive agent).

New claim 49 depends from and includes the subject matter of claim 1, 24, 25, 26, or 27. Claim 49 limits the first and second active agents to a particular combination of active agents, wherein the first active agent is a gastric acid inhibitor and the second active agent is a gastrointestinal emptying adjunct, otherwise known as a gastrointestinal prokinetic agent that promotes gastrointestinal emptying. This combination of types is supported by issued claim 12 and by the specification, which includes an exemplary formulation (Example 3) containing ranitidine (a gastric acid inhibitor, otherwise known as an H2 blocker or acid-suppressing drug) and cisapride (gastrointestinal emptying adjunct).

For all the above reasons, it is respectfully submitted that claims 1-49 are patentable over the references of record. An early Notice of Allowance of claims 1-49 is respectfully requested.

Respectfully submitted,

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CLAIMS AS AMENDED AND ADDED

1) (Amended) An improved multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the [drug] first active agent;

b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;

c) an inert, completely erodible or water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the [drug] second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

24) (New) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;

b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;

c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active

agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

25) (New) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;

b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;

c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.

26) (New) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;

b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;

c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and

d) an external coat comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.

27) (New) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and at least one osmotic agent for

controlled and continuous release of the first active agent;

b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;

c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and

d) an external coat comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.

28) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents each comprise a therapeutic agent.

29) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are the same.

30) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are different.

31) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into different environments of use.

32) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into the same environment of use.

33) (New) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.

34) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence from the group consisting of antibacterial, antihistamine, decongestant, anti-inflammatory, antiparasitic, antiviral, local anesthetic, antifungal, amoebicidal, trichomonocidal, analgesic, antiarthritic,

antiasthmatic, anticoagulant, anticonvulsant, antidepressant, antidiabetic, antineoplastic, antipsychotic, neuroleptic, antihypertensive, muscle relaxant, depressant, hypnotic, sedative, psychic energizer, tranquilizer, antiparkinson, muscle contractant, anti-microbial, antimalarial, hormonal, contraceptive, sympathomimetic, diuretic, hypoglycemic, ophthalmic, electrolyte, diagnostic and cardiovascular agent.

35) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence from the group consisting of pesticide, herbicide, insecticide, antioxidant, plant growth instigator, sterilization agent, catalyst, chemical reagent, food product, nutrient, cosmetic, vitamin, sterility inhibitor, fertility instigator, microorganism, flavoring agent, sweetener, and cleansing agent.

36) (New) The multi-layered osmotic device of claim 25, 26 or 27, wherein the inert, completely erodible or water soluble polymer coat comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer.

37) (New) The multi-layered osmotic device of claim 36, wherein the inert, completely erodible or water soluble polymer coat further comprises a second polymer.

38) (New) The multi-layered osmotic device of claim 36, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.

39) (New) The multi-layered osmotic device of claim 38, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).

40) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the inert, completely erodible or water soluble polymer coat comprises at least two different polymers.

41) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the delivery of the first active agent is delayed with respect to delivery of the second active agent.

42) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.

43) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first

active agent is pseudoephedrine and the second active agent is astemizole.

44) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is pseudoephedrine and the second active agent is loratadine.

45) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is diltiazem and the second active agent is enalapril.

46) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are theophylline.

47) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a decongestant and the second active agent is an antihistamine.

48) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a first antihypertensive agent and the second active agent is a different second antihypertensive agent.

49) (New) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a gastric acid inhibitor and the second active agent is a gastrointestinal emptying adjunct agent.